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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,574	01/10/2002	Jian Ni	PF375PID1	7011

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HUMAN GENOME SCIENCES INC  
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EXAMINER
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O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/041,574	<b>Applicant(s)</b> NI ET AL.	
	<b>Examiner</b> Eileen O'Hara	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-31, 33-37, 39, 41-47, 50-56, 58-63 and 65-71 is/are allowed.
- 6) ☒ Claim(s) 40, 48, 49, 64 and 72-120 is/are rejected.
- 7) ☒ Claim(s) 32, 38 and 57 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. The finality of the last action, Paper No. 12292003, is withdrawn for new grounds of rejection under 35 USC § 112 first and second paragraphs.

#### ***Status of Claims***

2. Claims 25-120 are pending in the instant application. Claims 25, 39, 40, 42, 43, 50, 56, 57, 63, 64, 66, 67, 73, 79, 80, 87, 88, 90, 91, 98, 104, 105, 111, 112, 114 and 115 have been amended and claims 121-125 have been canceled as requested by Applicant in the Paper filed February 20, 2004.

All claims are currently under examination.

#### ***Withdrawn Objections and Rejections***

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

#### ***New Objections and Rejections***

##### ***Claim Objections***

4.1 Claim 38 is objected to because of the following informalities: there is no period at the end of the sentence. Appropriate correction is required.

4.2 Claims 32, 57, 80 and 105 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent

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form, or rewrite the claim(s) in independent form. Claims 32, 57, 80 and 105 encompass the same antibodies as independent claims 25, 50, 73 and 98, and therefore do not further limit the parent claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 48, 49 and 72-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1 Claims 48, 49, 72, 96, 97 and 120 are indefinite because claims 48, 72, 96 and 120 are incomplete methods claims. Claims 48, 72, 96 and 120 are not written with the different methods steps clearly recited. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved. For example, in claim 48, part (b) is not a method step, and it doesn't relate to (a).

5.2 Claims 73-120 are indefinite because independent claims 73 and 98 encompass antibodies to a protein consisting of the specific amino acid residues recited (for example, amino acids 116-271) of the amino acid sequence encoded by the cDNA contained in ATCC Deposit Number 209037, and it is not clear if those amino acid sequences correspond to the same amino acid sequences of SEQ ID NO: 2. The residue numbering of the protein of SEQ ID NO: 2 starts at -40, so that amino acid 116 is actually the 156<sup>th</sup> residue from the start of the protein of SEQ

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ID NO: 2. It is not clear if the amino acid residues of the protein encoded by the cDNA of ATCC Deposit Number 209037 follows the same numbering as that of SEQ ID NO: 2 or not. This can be remedied by including a statement at the end such as “wherein the amino acids recited in (a) to (f) correspond to the numbering of SEQ ID NO: 2.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 40, 64, 88 and 112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims encompass an antibody or fragment thereof which is conjugated to a therapeutic or cytotoxic agent, which implies a therapeutic or cytotoxic use. Page 82, lines 4-18 and page 96, lines 3-34 of the specification discusses various therapeutic or cytotoxic agents that can be coupled to antibodies, however, there is no example in the specification or disclosure of why one of ordinary skill in the art would wish to target cells expressing the TR9 receptor with a therapeutic or cytotoxic agent. Administration of an antibody to TR9 conjugated to a cytotoxic agent would theoretically result in the death of any cell that expresses the receptor, and the specification has not disclosed why it would be desirable to destroy cells expressing the receptor, or why it would be beneficial to target a therapeutic agent to cells expressing the receptor.

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There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

It is acknowledged that the level of skill in the art is high, but for the reasons discussed above, due to the large quantity of experimentation necessary to determine the benefits of targeting TR9 expressing cells with a therapeutic or cytotoxic agent, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples and written description directed to same and the complex nature of the invention, undue experimentation would be required of the skilled artisan to make and/or use antibodies to TR9 conjugated to a therapeutic or cytotoxic agent.

### ***Conclusion***

- 7.1 Claims 25-31, 33-37, 39, 41-47, 50-56, 58-63 and 65-71 are allowed.
- 7.2 Claims 32, 38 and 57 are objected to.
- 7.3 Claims 40, 48, 49, 64 and 72-120 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, se <http://pair-direct.ispto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

A handwritten signature in black ink that reads "Eileen B. O'Hara". The signature is written in a cursive, flowing style.

Patent Examiner